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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,754	03/19/2001	Christopher Schuler	GC-425	8075

7590

03/01/2004

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300 Preston Avenue
Charlottesville, VA 22902

EXAMINER

MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
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3763

12

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,754

Applicant(s)

ED SCHULER, CHRISTOPHER

Examiner

Jennifer J Maynard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-5 and 9 is/are allowed.
- 6) ☒ Claim(s) 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

After further review, the finality of the rejection of the last Office action is withdrawn in favor of the rejections set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolation of collagen to produce contact lenses by using hyaluronidase, does not reasonably provide enablement for a method of treating eye disorders comprising the step of applying essentially protease-free hyaluronidase from *Streptomyces hyalurolyticus* to the eye, wherein the hyaluronidase is dissolved in a saline solution, and wherein said treating of an eye disorder is isolating of collagen to produce contact lenses by using hyaluronidase from *Streptomyces hyalurolyticus*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant's specification, Page 8, lines 14-19, refers to Fedorov et al. (US 6,037,144 A) for teaching a method of preparing artificial lenses, the Examiner failed to locate reference to a step of applying essentially protease-free hyaluronidase from *Streptomyces hyalurolyticus* to the eye, wherein the hyaluronidase is dissolved in a saline solution, in the method of isolating of collagen to produce contact lenses by using hyaluronidase from

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Streptomyces hyalurolyticus within the Fedorov et al.'s patent or Applicant's specification. Thus it is the Examiner's position that Applicant's specification while enabling for the preparation of artificial lenses by using *Streptomyces hyalurolyticus* to isolate collagen, is not enabling for applying essentially protease-free hyaluronidase from *Streptomyces hyalurolyticus* to the eye during the preparation of the artificial lenses.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knepper et al. (Invest. Ophthalmol. Vis. Sci. 1984 March; 25(3):286-93) in view of Kaneko et al. (US 3,728,223 A).

Knepper et al. disclose a method of infusing a hyaluronidase derived from *Streptomyces* into a rabbit's eye to effectively decrease aqueous outflow resistance.

Knepper et al. fail to teach utilizing a hyaluronidase derived from *Streptomyces hyalurolyticus*, which is characterized as being essentially free of contaminating protease and has a hyaluronidase activity of at least about 10 TRU.

Kaneko et al. disclose a process of producing and purifying a clinically stable hyaluronidase from *Streptomyces hyalurolyticus*.

It would have been obvious to one having ordinary skill in the art to have utilized a purified form of hyaluronidase derived from *Streptomyces hyalurolyticus* taught by Kaneko et al., as it was known to be more stable and more specific, as well as being biocompatible, non-toxic and therapeutic at certain dosage levels.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knepper et al. (Invest. Ophthalmol. Vis. Sci. 1984 March; 25(3):286-93) in view of Kaneko et al. (US 3,728,223 A) as applied to claim 7 above, and further in view of Sawyer et al. (US 4,820,516 A).

Knepper et al. in view of Kaneko et al. teach the invention as claimed with the exception of the treatment being for glaucoma, thrombosis, detached or impending detached retina, or for the non-surgical removal of obstructions.

Sawyer et al. discloses the use of hyaluronidase for stimulating flow of physiological fluid in the eye for treatment of glaucoma and other eye disorders in which some dissolution of the vitreous or improvement of circulation of physiological fluids in or about the eye would be useful; for example, to assist in the non-surgical removal of various obstructions, or to alleviate intraocular pressure, thrombosis in the eye, and in the treatment of detached or impending detached retinas.

It would have been obvious to one having ordinary skill in the art to have relied upon the *Streptomyces hyalurolyticus* hyaluronidase as taught by Knepper et al. in view of Kaneko et al. to treat glaucoma or to assist in non-surgical removal of various obstructions in the eye as disclosed by Sawyer et al., as those conditions are directly related to the development of

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resistance in the eye's aqueous outflow pathway which is effectively decreased by the application of *Streptomyces* hyaluronidase to the eye.

Allowable Subject Matter

Claims 1, 3-5 and 9 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

After further reviewing the prior art of record in view of Applicant's arguments found on Pages 10-13 of the Appeal Brief filed 17 November 2003, the Examiner has found Applicant's assertions persuasive and has removed the rejections of record.

Response to Arguments

Applicant's arguments with respect to claims 6-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

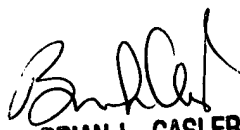
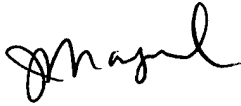
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J Maynard



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